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| APPLICATION NO. FILING DATE |           | NG DATE    | FIRST NAMED INVENTOR    | ATTORNEY DOCKET NO. | CONFIRMATION NO. |  |
|-----------------------------|-----------|------------|-------------------------|---------------------|------------------|--|
| 10/619,928 07/15/2003       |           | 15/2003    | Richard A. Terwilliger  | WORLD-01000USB      | 6815             |  |
| 23910                       | 7590      | 07/14/2005 |                         | EXAMINER            |                  |  |
| FLIESLER<br>FOUR EMB        | •         |            | GILBERT, S              | GILBERT, SAMUEL G   |                  |  |
| SUITE 400                   | AKCADEK   | O CENTER   | ART UNIT                | PAPER NUMBER        |                  |  |
| SAN FRANC                   | CISCO, CA | 94111      | . 3736                  |                     |                  |  |
|                             |           | •          | DATE MAILED: 07/14/2005 |                     |                  |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| U.S. Patent and Trademark Office<br>PTOL-326 (Rev. 1-04)  | Office Act  | tion Summa  | r <b>y</b> Pa  | rt of Paper No./Mail D | ate 20050711 |  |  |  |  |  |
|---|---|-------------|--|------------------------|--------------|--|--|--|--|--|
| Attachment(s)  1) ☒ Notice of References Cited (PTO-892)  2) ☐ Notice of Draftsperson's Patent Drawing Review  3) ☒ Information Disclosure Statement(s) (PTO-1449 Paper No(s)/Mail Date 2/4/2005.   |   |             | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: |                        | 0-152)       |  |  |  |  |  |
| <ul> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |   |             |  |                        |              |  |  |  |  |  |
| 1. Certified copies of the prior  | 1. Certified copies of the priority documents have been received.   |             |  |                        |              |  |  |  |  |  |
| 12) Acknowledgment is made of a claim a) All b) Some * c) None of   | 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |             |  |                        |              |  |  |  |  |  |
| Priority under 35 U.S.C. § 119  |   |             |  | , n                    |              |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |   |             |  |                        |              |  |  |  |  |  |
| Applicant may not request that any ol   | 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). |             |  |                        |              |  |  |  |  |  |
| 9) The specification is objected to by  |   |             | <b>7</b>   |                        |              |  |  |  |  |  |
| Application Papers  |   |             |  |                        |              |  |  |  |  |  |
| · · · · · · · · · · · · · · · · · · ·   | 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement.   |             |  |                        |              |  |  |  |  |  |
| 6)⊠ Claim(s) <u>1-14 and 16-29</u> is/are rejected.   |   |             |  |                        |              |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.   |   |             |  |                        |              |  |  |  |  |  |
| 4) Claim(s) 1-14 and 16-29 is/are pending in the application.   |   |             |  |                        |              |  |  |  |  |  |
| Disposition of Claims   |   |             |  |                        |              |  |  |  |  |  |
| closed in accordance with the pra   | ictice under Ex   | x parte Qu  | ayle, 1935 C.D. 11, 45   | 3 O.G. 213.            |              |  |  |  |  |  |
|   | since this application is in condition for allowance except for formal matters, prosecution as to the merits is   |             |  |                        |              |  |  |  |  |  |
| 2a) This action is FINAL.   | 2b)⊠ This   | •           | on-final.  |                        |              |  |  |  |  |  |
| 1) Responsive to communication(s)   | filed on 28 An  | oril 2005.  |  |                        |              |  |  |  |  |  |
| earned patent term adjustment. See 37 CFR 1.704(b)  Status  | <i>,</i> -  |             |  |                        |              |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any |   |             |  |                        |              |  |  |  |  |  |
| Period for Reply  |   |             |  | ·                      |              |  |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address   |   |             |  |                        |              |  |  |  |  |  |
| Office Action Summary   |   | Examiner    |  | Art Unit               | -            |  |  |  |  |  |
|   |   | 10/619,92   | 8  | TERWILLIGER ET AL.     |              |  |  |  |  |  |
|   |   | Application | on No.   | Applicant(s)           |              |  |  |  |  |  |

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#### 1. **DETAILED ACTION**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-14 2. Claims 1-14, 16, 17, 19, 21-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Candelaria (6,497,646) in view of Horowitz(4,815,449) and Rapach et al(2004/0015037).

Candelaria et al discloses a strand that is used to treat the body and teaches (column 6, lines 15-35) that it is known to determine a treatment plan to form a ribbon or strand of seeds and spacers depending on the desired tissues to be treated.

Candelaria et al states that the seeds and spacers may be of any size and may be positioned in any configuration within the container depending on the determined plan.

The seeds and spacers are positioned and affixed in the container in the order and spacing that have been determined. Elements –108- are spacers and there does not appear to be a distal end spacer.

Candelaria et al discloses the claimed apparatus and methods except prefabricated spacers are used and the distal end spacing is not custom.

Horowitz teaches the use of a prefabricated distal end spacer figure 8 element – 56- the spacer nearest to the point –52-. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a prefabricated spacer at the

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distal end of Candelaria et al as taught by Horowitz to provide the ability to position the distal seed in the proper location for implantation as taught by Horowitz.

Rapach et al teaches a method of creating a treatment strand by molding a polymeric material around the seeds (see paragraphs 43-50). Rapach et al also teaches using a bioabsorbable polymer (see paragraph 38). Therefore a modification of the combination of the combination of Candelaria et al and Horowitz such that the strand is made by molding would have been obvious in view of Rapach et al which teaches that it is well known to make such a strand by molding a polymer around seeds. Molding the treatment strand provides the benefit of an automated manufacturing process as taught by Rapach et al, paragraph[0013]. It is the examiners position that the spacers can be made of any desirable length including the distal end spacer as taught by Candelaria et al.

A plurality of strands made from the same mold would have the same length using different molds would produce a plurality of different strands.

3. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Candelaria in view of Horowitz and Rapach et al as applied to claims above, and further in view of Yu(6,200,255).

The above combination fails to specifically teach that a computer program is used to create the treatment plan. Yu teaches a planning engine for radiotherapy and discloses that it is well known to use a computer algorithm to create the treatment plan (see

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paragraphs 7, 10-11). Therefore a modification of the above combination such that a computer is used to create the treatment plan would have been obvious in view of the teachings of Yu. Further it is well known to use computer technology to perform such task's since the computers allow for much faster processing than is possible if done by humans.

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## Double Patenting

Claims 1-14 and 16-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 10/397,940 in view of Horowitz(4,815,449). The claims of 10/397,940 teach a method and apparatus as claimed including molding a treatment strand without using prefabricated spacers and the spacers can be of any desired custom, however, distal end spacers are not set forth. Horowitz teaches using a distal end spacer Figure 8 element –56- nearest point –52-. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include distal end spacers in the molding process as taught by 10/397,940 to provide appropriate spacing as taught by Horowitz.

### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenberg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Samuel G. Gilbert Primary Examiner Art Unit 3736